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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,698	HUNG ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

It is noted that the claims of the instant application have been determined to include linking claims. **Claim 1 link(s) Groups I-III** as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

I. Claims 2-11, drawn to a mutant Bik polypeptide comprising **anti-cell proliferative activity**, classified in class 530, subclass 350.

II. Claims 2-11, drawn to a mutant Bik polypeptide comprising **pro-apoptotic activity**, classified in class 530, subclass 350.

III. Claims 2-11, drawn to a mutant Bik polypeptide comprising **both anti-cell proliferative activity and pro-apoptotic activity**, classified in class 530, subclass 350.

It is noted that the claims of the instant application have been determined to include linking claims. **Claim 12 link(s) Groups IV-VI** as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 12. Upon the allowance of the linking claim(s), the restriction requirement

as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

IV. Claims 13-26, 41, 42, drawn to a method comprising administering to a cell a Bik **polypeptide** having an amino acid substitution, classified in class 435, subclass 7.1.

V. Claims 13, 27-33, 41, 42, drawn to a method comprising administering to a cell a **nucleic acid encoding a Bik polypeptide having an amino acid substitution at Thr^{33}**, classified in class 435, subclass 6.

VI. Claims 13, 34-42, drawn to a method comprising administering to a cell a **nucleic acid encoding a Bik polypeptide having an amino acid substitution at Ser^{35}**, classified in class 435, subclass 6.

It is noted that the claims of the instant application have been determined to include linking claims. **Claim 43 link(s) Groups VII-IX** as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 43. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking

claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

VII. Claims 44-58, drawn to a method of inhibiting cell proliferation comprising contacting a cell with a mutant Bik polypeptide, wherein the mutant polypeptide has **anti-cell proliferative activity**, classified in class 514, subclass 2.

VIII. Claims 44-58, drawn to a method of inhibiting cell proliferation comprising contacting a cell with a mutant Bik polypeptide, wherein the mutant polypeptide has **pro-apoptotic activity**, classified in class 514, subclass 2.

IX. Claims 44-58, drawn to a method of inhibiting cell proliferation comprising contacting a cell with a mutant Bik polypeptide, wherein the mutant polypeptide has **both anti-cell proliferative activity and pro-apoptotic activity**, classified in class 514, subclass 2.

X. Claims 59-63, drawn to a method of treating cancer in an individual comprising administering a polynucleotide encoding a Bik polypeptide

having a substitution wherein the polynucleotide is comprised in a liposome, classified in class 514, subclass 44.

Additionally, Applicants must elect a single amino acid substitution [Thr^{33} to Asp^{33}, Ser^{35} to Asp^{35}, or both] as each nucleotide sequence encoding a mutated Bik presents a structurally and functionally *distinct* invention not a species.

XI. Claims 64-71, drawn to a polynucleotide comprising a nucleic acid sequence encoding a mutant Bik polypeptide, classified in class 536, subclass 23.1.

It is noted that the claims of the instant application have been determined to include linking claims. **Claim 72 link(s) Groups XII and XIII** as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 72. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

XII. Claims 73, 74, drawn to a method of sensitizing a tumor cell to a chemotherapeutic agent comprising delivering to the cell a mutant Bik composition, wherein the composition is a **mutant Bik polypeptide**, classified in class 514, subclass 2.

XIII. Claims 73, 75, drawn to a method of sensitizing a tumor cell to a chemotherapeutic agent comprising delivering to the cell a mutant Bik composition, wherein the composition is a **polynucleotide encoding a mutant Bik polypeptide**, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group XI is related to the protein of Groups I-III by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups XI and I-III together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups XI and I-III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have

described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. Furthermore, a search of the nucleic acid molecules of Group XI would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group I-III. As such, it would be burdensome to search the inventions of Groups XI and I-III.

The inventions of Groups IV-X, XII, and XIII are materially distinct methods which differ at least in objectives, method steps and reagents. For example, Groups IV-VI are drawn to different methods comprising administering structurally and functionally different products. Groups VII-IX are drawn to the different objective of inhibiting cell proliferation comprising a polypeptide with functionally different properties. Group X is drawn to the different objective of treating cancer comprising administering a polynucleotide. Groups XII and XIII are drawn to the different objective of sensitizing a tumor cell to a chemotherapeutic agent wherein each Group administers a structurally and functionally different composition. Thus, the methods are materially distinct from the method elected and differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success and would invoke a high burden of search.

Inventions I-III, XII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Groups I-III can be used in affinity chromatography.

Inventions I-III and VII-IX are related, respectively, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Groups I-III can be used in affinity chromatography.

Inventions XI and V, VI, X, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Groups XI can be used for hybridization assays or affinity chromatography.

The product of Groups I-III are not used in the methods of Groups V, VI, X, XIII. The product of Group XI is not used in the methods of IV, VII-IX, and XII.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, and because some Groups have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

SPECIES ELECTION

Species Election for Groups I-III

A. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of the claimed invention: a Bik polypeptide comprising an amino acid substitution at: **Thr^{33}** (claim 5, 6, 8), **Ser^{35}** (claim 5, 7, 8), or **both Thr^{33} and Ser^{35}** (claim 5, 8).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Species Election for Group IV

B. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of the claimed invention: a Bik polypeptide comprising an amino acid substitution at: **Thr^{33}** (claim 13, 14), **Ser^{35}** (claim 13, 15), or **both Thr^{33} and Ser^{35}** (claim 13).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 12 is generic.

C. This application contains claims directed to the following patentably distinct, etiologically and functionally distinct proliferative disorder species of the claimed invention: **cancer** (claim 20-23) or **restenosis** (claim 24).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 12 is generic.

Should Applicant elect "cancer" in C, Applicant must elect a characteristic of the cancer in D:

D. This application contains claims directed to the following patentably distinct, structurally and functionally distinct cancer species of the claimed invention: **estrogen receptor positive, EGF receptor overexpressing, Her2/neu-overexpressing, not Her2/neu-overexpressing, Akt overexpressing, androgen independent, androgen dependent** (claim 22).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 12 is generic.

Claim 21 will be examined as drawn to the elected species in D.

Species Election for Group V

E. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of tissue-specific control sequences of the claimed invention: **breast cancer tissue-specific control sequence (claim 31),**

prostate cancer tissue-specific control sequence (claim 32), or pancreatic cancer tissue-specific control sequence (claim 33).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 12 is generic.

Species Election for Group VI

F. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of tissue-specific control sequences of the claimed invention: **breast cancer tissue-specific control sequence (claim 38), prostate cancer tissue-specific control sequence (claim 39), or pancreatic cancer tissue-specific control sequence (claim 40).**

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 12 is generic.

Species Election for Groups VII-IX

G. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of the claimed invention: a Bik polypeptide comprising an amino acid substitution at: **Thr^{33}** (claim 48, 49), **Ser^{35}** (claim 48, 50), or **both Thr^{33} and Ser^{35}** (claim 48).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 43 is generic.

Species Election for Group X

H. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of tissue-specific control sequences of the claimed invention: **breast cancer tissue-specific control sequence (claim 61), prostate cancer tissue-specific control sequence (claim 62), or pancreatic cancer tissue-specific control sequence (claim 63).**

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 59 is generic.

Species Election for Group XI

I. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of tissue-specific control sequences of the claimed invention: **breast cancer tissue-specific control sequence (claim 67), prostate cancer tissue-specific control sequence (claim 68), or pancreatic cancer tissue-specific control sequence (claim 69).**

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 64 is generic.

J. This application contains claims directed to the following patentably distinct, structurally and functionally distinct species of the claimed invention: a Bik polynucleotide encoding a polypeptide comprising an amino acid substitution: **Thr^{33} to Asp^{33}**, **Ser^{35} to Asp^{35}**, or **both** (claim 70).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 64 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER